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FEB 2 1 2006

Attorney Docket No.: Enz-7(P)(C3)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jannis Stavrianopoulos et al.

Serial No.:

08/486,070

Group Art Unit: 1631

Filed:

June 7, 1995

Primary Exam'r: John S. Brusca

For:

NUCLEIC ACIDS FIXED OR IMMOBILIZED TO NON-POROUS SOLID SUPPORT, AND SYSTEM, ARRAY AND NON-POROUS GLASS OR PLASTIC SOLID SUPPORT COMPRISING SUCH FIXED

OR IMMOBILIZED NUCLEIC ACIDS

Confirmation No.:

CERTIFICATE OF FACSIMILE TRANSMISSION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence (total of 100 pages including this sheet) comprising:

> Sixth Supplemental Information Disclosure Statement Under 37 C.F.R. §§1.56 & 1.97-1.98 (& 9 Exhibits)

was sent to the United States Patent and Trademark Office by telefax to (571) 273-8300.

Respectfully submitted,

Date: February 21, 2006

Ronald C. Fedus, Reg. No. 32,567

Attorney for Applicants Enzo Life Sciences, Inc. c/o Enzo Biochem, Inc.

527 Madison Avenue, 9th Floor New York, NY 10022-4304 Telephone (212) 583-0100

Facsimile (212) 583-0150

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Stavrianopoulos et al.

Serial No.:

08/486,070

Filed:

June 7, 1995

For: NUCLEIC ACIDS FIXED OR IMMOBILIZED TO)

NON-POROUS SOLID SUPPORT, AND

SYSTEM, ARRAY AND NON-POROUS GLASS) OR PLASTIC SOLID SUPPORT COMPRISING) SUCH FIXED OR IMMOBILIZED NUCLEIC

ACIDS (As Previously Amended)

BECEIVED CENTRAL FAX CENTER

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Group Art Unit: 1631

Primary Exam'r: John S. Brusca

527 Madison Avenue, 9th Floor New York, NY 10022-4304 February 21, 2006

FILED VIA FACSIMILE TRANSMISSION TO: (571) 273-8300

Mail Stop No-Fee Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§1.56 & 1.97-1.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following eight (8) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

Enz-7(P)(C3)

Stavrianopolous et al Serial No.: 08/486,070 Filed: June 7, 1995

Page 2 [Sixth Supplemental IDS - February 21, 2006]

CERTIFICATE OF TRANSMISSION

I hereby certify that this paper (Sixth Supplemental Information Disclosure Statement Under 37 C.F.R. 551.56 & 1,97-1.98) (along with any documents referred to as attached or enclosed) is being facsimile transmitted to the United States Patent and Trademarks (Fax No. 571-273-8300) on February 21, 2006.

Ronald C. Fedus Reg. No. 32,567 F<u>CB 21 20</u>06

Date

Reg. No. 32,567

- 1. Falkow et al., U.S. Patent No. 4,358,535, issued November 9, 1982 [Exhibit 1];
- Heller et al., European Patent Publication No. 0 070 687,² published on January 26, 1983 [Exhibit 2];
- 3. Haugen et al., "Monoclonal antibody to aflatoxin B₁-modified DNA detected by enzyme immunoassay," <u>Proc. Natl. Acad. Sci. (USA)</u> 78:4124-4127 (1981) [Exhibit 3];
- Vogelstein and Gillespie, "Preparative and analytical purification of DNA from agarose," <u>Proc. Natl. Acad. Sci. (USA)</u> 76:615-619 (1979) [Exhibit 4];

¹ Cited and submitted as Exhibit 1 in Applicants' June 2, 1994 Information Disclosure Statement Under 37 C.F.R. §§1.56 & 1.99 in the previous application Serial No. 07/967, 646, filed on October 29, 1992.

Also cited in January 19, 1988 and November 29, 1988 Office Actions mailed in connection with predecessor application Serial No. 06/732,374, filed on May 9, 1985.

Also cited in November 9, 1984 Office Action mailed in connection with the first-filed application in this family, Serial No. 06/461,469, filed on January 27, 1983.

² Cited and submitted as Exhibit 25 in Applicants' June 2, 1994 IDS filed in Serial No. 07/967,646, filed on October 28, 1992.

Stavrianopolous et al Serial No.: 08/486,070 Filed: June 7, 1995

Page 3 [Sixth Supplemental IDS -- February 21, 2006]

- Munns and Liszewski, "Antibodies specific for Modified Nucleosides: An Immunochemical Approach for the Isolation and Characterization of Nucleic Acids," in <u>Progress in Nucleic Acid Research and Molecular Biology</u>, Academic Presss, Inc., Vol. 24, pages 109-165 (1980) [Exhibit 5];
- 6. Nagata et al., "Quantification of pictogram levels of specific DNA immobilized in microtiter wells," Federation of European Biochemical Societies (FEBS) 183:379-382 (April 1985) [Exhibit 6];
- 7. Sedlacek et al., "A New Method For Fluorescence Immunoassay Using Plane Surface Solid Phases (FIAPS)," <u>Journal of Immunological Methods</u> <u>26</u>:11-24 (1979) [Exhibit 7]; and
- 8. Van Der Laken et al., "Measurement of O6-ethyldeoxyguanosine and N-(deoxyguanosin-8-yl)-N-acetyl-2-aminofluorene in DNA by high sensitive enzyme immunoassays," <u>Carcinogenesis</u> 3:569-572 (1982) [Exhibit 8].

Copies of the above-listed eight documents have been provided as Exhibits 1-8.

Applicants have also provided as Exhibit 9 two pages of the Form PTO-SB/08A (07-05) with these eight documents listed thereon. Although the provisions of 37 C.F.R. §1.98(a)(2)(ii) do not require the submission of U.S. patents, Applicants have provided nevertheless a copy of U.S. Patent No. 4,358,535 including the Reexamination Certificate issued on May 13, 1986.

It is respectfully requested that these eight above-listed documents be made of record by the U.S. Patent and Trademark Office in this application.

These eight above-listed documents were recently brought to the attention of Applicants' undersigned attorney from papers filed by defendants in two litigations involving *inter alia*, U.S. Patent No. 4,994,373. The '373 Patent is related to the present application, including the first-filed application in the family, U.S. Patent Application Serial No. 06/461,469, filed January 27, 1983.

FEB. 21. 2006 11:37AM ENZO BIOCHEM NO. 8098 P. 5

Stavrianopolous et al Serial No.: 08/486,070 Filed: June 7, 1995

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The two litigations are: Enzo Biochem, Inc. and Enzo Life Sciences, Inc. v. Amersham PLC et al., Civil Action No. 02-CV-8448 (JES), Southern District of New York, and Enzo Biochem, Inc. & Yale University v. Applera Corp. and Tropix, Inc., Civil Action No. 3:04-cv-929, District of Connecticut.

Applicants would also like to bring attention to two developments in the European Patent Office (EPO) involving related foreign counterparts. In one development, European Patent No. 0 117 440 B1 was revoked by a decision issued on June 23, 1997 by the EPO's Opposition Division. In the other development, the Examining Division of the EPO issued a Communication Under Rule 51(4) EPC on June 21, 2004 informing of its intention to grant a European patent for EP 0 525 821, which is a divisional application of the aforementioned EP 0 117 440 B1. Applicants' European associates have just informed them that the EPO has just issued a decision to grant European Patent No. 0 525 821. The mention of the grant will be published on March 29, 2006 and the patent will come into effect as of that date.

Applicants respectfully point out that the submission of the above documents is neither an admission that they are prior art, nor that they are material to the patentability of any claims in their application.

Consideration of these eight documents and the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP \$609 are respectfully requested. Listing of these documents on the face of the patent issuing from this application is also respectfully requested.

Pursuant to 37 C.F.R. §1.97(c)(2), The Patent and Trademark Office is hereby authorized to charge Deposit Account No. 05-1135 in the amount of \$180.00 as set forth in §1.17(p). No other fee or fees are believed to be due in

Stavrianopolous et al Serial No.: 08/486,070 Filed: June 7, 1995

Page 5 [Sixth Supplemental IDS -- February 21, 2006]

connection with this paper. In the event that any other fee or fees are due, however, authorization is given to charge the amount of any such fee(s) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,

Ronald C. Fedus

Registration No. 32,567 Attorney for Applicants

ENZO LIFE SCIENCES, INC. c/o Enzo Biochem, Inc. 527 Madison Avenue, 9th Floor New York, NY 10022-4304 Tel. (212) 583-0100 Fax (212) 583-0150

Sheet 1

PTO/SB/08A (07-05)

Under the Paperwork Reduction Act of 1995, no persons are required to re-	U.S. Patent and Tracemark Office; U.S. DEPARTMENT OF COMMERC U.S. Patent and Tracemark Office; U.S. DEPARTMENT OF COMMERC spend to a collection of information unities it contains a valid OMB control number
Substitute for form 1449/PTO	Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Application Number 08/486,070 Filling Date June 7, 1995 First Named Inventor Jannis Stavrianopoulos Art Unit 1631 Examiner Name John S. Brusca Attorney Docket Number Enz-7(P)(C3)

Examiner	Cita		U. S. PATEN	TDOCUMENTS	
inilials*	Cite No.1	Document Number Number-Kind Code ^{2 (F known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columna, Unes, Where Refevant Passages or Refevant Figures Appear
	1	^{US-} 4,358,535	11-09-1982	FALKOW ET AL.	
	1	US- B1 4,358,535	05-13-B6	FALKOW ET AL.	Reexamination Certificate
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		FORE	IGN PATENT DOCL	MENTS		
Examiner Cite Foreign Patent Doo	Foreign Patent Document	Patent Document Publication Date	Name of Petentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Γ	
		Country Code ⁸ "Number " "Kind Code ⁶ (If known)	MM-DD-YYYY		Or Relevant Figures Appear	τ°
	2	EPO 0 070 687	07-14-1982	HELLER ET AL.		
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Examiner	Date	
Signature	Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant. Applicant's unique citation designation number (options). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Transtation is attached.
This collection of immedian is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and automitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Paterd and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/\$B/08B (07-05) Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Tradomark Office; U.S. DEPARTMENT OF COMMERCE

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			Application Number	08/486,070	
INFORMATION DISCLOSURE		Filing Date	June 7, 1995		
STATEMENT BY APPLICANT		First Named Inventor	Jannis Stavrianopoulos		
(Use as many sheets as nocessary)		Art Unit	1631		
			Examiner Name	John S. Brusca	-
Sheet 2	of	2	Attorney Docket Number	Enz-7(P)(C3)	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	3	HAUGEN ET AL., Monoclonal antibody to aflatoxin B1-modified DNA detected by enzyme immunoassay," PNAS, 78, pp. 4124-4127 (1981)	
	4	VOGELSTEIN, B. AND GILLESPIE, D., Preparative and Analytical Purification of DNA From Agarose, Proc. Natl. Acad. Sci. USA Vol. 76, No. 2, pp. 615-619, February 1979	
	5	MUNNS AND LISZEWSKI, "Antibodies specific for Modified Nucleosides et al.," Progr. Nucl. Acid Res. & Molec. Bio., Academic Press, Inc., Vol. 24, pp. 109-165 (1980)	
	6	NAGATA ET AL., "Quantification of picogram levels of specific DNA immobilized in microtiter wells," FEBS, 183, pp. 379-382 (April 1985)	
	7	SEDLACEK, H. et al., A New Method for Fluorescence Immunoassay Using Plane Surface Solid Phases (FIAPS), J. Immun. Methods, 26, (1979) 11-24	
ï	6	VAN DER LAKEN ET AL., "Measurement of O6-ethyldeoxyguanosine and N-(deoxyguanosin-8-yl)-N-acetyl-2-aminofluorene in DNA et al.," Carcinogenesis, 3, 569-572 (1982)	
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Examiner	Date	
Signature	 Considered	

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and salect option 2.

^{*}EXAMINER: Initial if reference considered, whether or not classion is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of Information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is eathered to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time with vary depending upon the individual case. Any comments on the amount of time you require to complete life form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of Information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2908. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.